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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,983	07/22/2002	Roberto Alcantara Martins Zucchetti	32286R010	9146

441 7590 09/21/2005

SMITH, GAMBRELL & RUSSELL, LLP  
1850 M STREET, N.W., SUITE 800  
WASHINGTON, DC 20036

EXAMINER

YEBASSA, DESTA LETTA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,983

Applicant(s)

ZUCCHETTI ET AL.

Examiner

Desta L. Yebassa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-16,18-29 and 31-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-16,18-29 and 31-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt is acknowledged of applicant's remarks and amendment filed on 06/03/05.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 5-8, 16, 18, 20-23, 26-29, 31-34, and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,573,299 to Petrus.

Petrus discloses a composition comprising ascorbic acid, propylene glycol, EDTA, and glutathione, which read on the instant antioxidant, oxygen removing compound, metallic ion sequestering compound and oxidation reaction reverting compound respectively (examples 1 and 2). Instant claim 1 recites a process of contacting antioxidant with the other components. While Petrus does not explicitly state the process, preparing a composition without contacting the components comprising the composition is not possible. Accordingly, the claimed process is inherent to the composition of Petrus. With respect to the claims directed to two-phase composition, examiner notes that the instant claims recite components in the two phases that are water-soluble. However, upon mixing two miscible phases a separate distinction is

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maintained between the phases and only result in a single phase. Accordingly, independent claim 28 and claims dependent from claim 28 are interpreted as single-phase composition. Petrus discloses glycerin (example 1), which reads on the claimed hydrant. Thus, Petrus anticipates instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-3, 5-14, 16, 18, 20-29, 31-38 and 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,193,956 to Liu et al.

Liu teaches stable antioxidant compositions comprising propylene glycol, ascorbic acid, disodium EDTA, and water, in addition to the antioxidants such as vitamin A. Liu teaches addition of chelating agents to each of the oil and water phases, addition of emulsifiers such as cetearyl alcohol and cetearyl glucoside (col. 4), emollients (col. 7), oil soluble antioxidants and water-soluble antioxidants such as sodium bisulfite, ascorbic acid (col. 8, lines 3-10), humectants including glycerol, propylene glycol (col. 8, lines 64-67), moisturizing agents including propylene glycol, allantoin (col. 10, lines 20-28). Example 1 teaches preparing two different phases (oil and water phase) containing respective ingredients and lists the claimed components i.e., propylene glycol, and ascorbic acid, disodium EDTA. Further, the compositions of examples 9B, 12, 13 (col. 27-28), contain allantoin, sodium bisulfite and emulsifiers (col. 6, lines 45-59).

With respect to the claimed two-phase aqueous composition, as explained in the previous section, upon mixing of two miscible phases, the respective phases do not remain in separate phases and instead result in a single phase. Accordingly, the claimed two-phase composition reads on a single phase and Liu clearly teaches the aqueous phase containing claimed components. With respect to the steps of contacting in preparing the compositions, again as explained before, adding the components in order to prepare a composition is inherent to the composition. While Liu teaches

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ascorbic acid, EDTA, glycerin, sodium metabisulfite etc., in the claimed amounts, Liu does not teach the exact amounts of propylene glycol. However, Liu teaches propylene glycol as a humectant and skin moisturizer and accordingly optimizing the amount of the same to achieve an art recognized effect would have been obvious for a skilled artisan. Further, Liu teaches preparing emulsion containing antioxidant for stability and achieving the desired droplet size. Accordingly, choosing a desired droplet size of the antioxidant composition without losing the stability of the composition would have been within the scope of a skilled artisan.

3. Claims 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (US 6,573,299) as applied to claims 1-3, 5-8, 16, 18, 20-23, 26-29, 31-34 and 36-38 above, and further in view of US 5,470,874 to Lerner.

Petrus teaches a composition for treating aging eye, age related eye changes such as dry skin, wrinkles, keratoses, age spots etc., comprising ascorbic acid, propylene glycol, glutathione, propylene glycol. Petrus does not teach the claimed proanthocyanidines, however, teaches addition of other potent antioxidants such as glutathione, alpha-lipoic acid etc., to the composition (col. 10-11).

Lerner teaches a skin care composition comprising ascorbic acid and proanthocyanidines, as the composition possesses a sunscreen and collagen repair properties. Lerner teaches that both vitamin C and proanthocyanidines have superior free radical scavenging properties and are useful in collagen synthesis, optimum maintenance of immune system, etc (col.2). Lerner also teaches addition of propylene

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glycol, EDTA, xanthan gum etc., in the composition (col. 4). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add proanthocyanidines of Lerner to the composition of Petrus comprising ascorbic acid as an active agent because Lerner suggests that both the components have superior antioxidant activity and that a combination of vitamin C and proanthocyanidines result in an enhanced tissue healing response time, without any irritating side effects and yet long shelf life.

4. Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,193,956 to Liu et al as applied to claims 1-3, 5-14, 16, 18, 20-29, 31-38 and 41-48 above,

Liu teaches antioxidant composition, as explained above. But fails to teach the claimed OPC (proanthocyanidines). However, Liu suggests that more than one antioxidant (water or oil soluble) may be included in the composition.

Lerner teaches a skin care composition comprising ascorbic acid and proanthocyanidines, as the composition possesses a sunscreen and collagen repair properties. Lerner teaches that both vitamin C and proanthocyanidines have superior free radical scavenging properties and are useful in collagen synthesis, optimum maintenance of immune system, etc (col.2). Lerner also teaches addition of propylene glycol, EDTA, xanthan gum etc., in the composition (col. 4). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add proanthocyanidines of Lerner to the composition of Liu comprising ascorbic acid because Lerner suggests that both the components have superior antioxidant activity

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and that a combination of vitamin C and proanthocyanidines result in an enhanced tissue healing response time, without any irritating side effects and yet long shelf life.

5. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (US 6,573,299) and US 5,470,874 to Lerner as applied to claims 1-4, 5-8, 16-19, 20-23, 26-34 and 36-38 above, and further in view of KR 9210246 (KR).

Petrus teaches stable antioxidant compositions containing ascorbic, but fails to teach proanthocyanidines (PRO). Lerner teaches an increased antioxidant activity with a combination of vitamin C and PRO (both antioxidants). Petrus and Lerner do not teach ceramides, as claimed.

KR teaches a composition for inhibiting free radicals comprising ascorbate, tocopherol, ceramides sphingolipids etc (abstract). The amount of ceramides taught by KR is within the claimed range. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add ceramides of KR to the composition of Petrus containing vitamin C and PRO (Lerner) because KR also teaches a antioxidant composition to inhibit free radical activity like that of Petrus and Lerner, thus constituting analogous art. Further, Lerner also suggests that a combination of antioxidant compounds further increases the activity. Accordingly, a skilled artisan would have expected a synergistic antioxidant activity by with a combination of ascorbic acid, ceramides and PRO.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11



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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/030,977. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant set of claims and the copending claims recite a composition comprising primarily an antioxidant, and a metallic ion-sequestering agent, a deoxygenating agent (which is claimed as a oxidation reaction reverting agent in the / instant claims). The dependent claims of the copending application recite the same specific metallic ion-sequestering agent, a deoxygenating agents as in the instant claims. Further, the copending claims also recite PRO and ceramides in the composition, which are also claimed in the instant application. Instant claims 28-45 recite two-phase composition, which reads on the bi-phase composition of the copending claims. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the claimed two-phase composition comprising antioxidant, sequestering agent, oxidation

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reverting agent and other ceramides (which are also claimed in the instant) from the copending claims with an expectation to achieve the desired antioxidant activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-45 are directed to an invention not patentably distinct from claims 1-21 of commonly assigned 10/030,977. Specifically, both sets of claims, as explained, are directed to antioxidant composition comprising the same sequestering agents, moisturizers, reducing agents etc (see above).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP j 2302). Commonly assigned 10/030,977, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (9 or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(9 or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### **Response to Arguments**

#### **1. *Obviousness-type double patenting rejection***

In response to the obviousness-type double patenting rejection, applicants requested the rejection to be held in abeyance until allowable subject matter is indicated at which point applicants will address the issue of whether to file a Terminal Disclaimer. However, no such has been filed. Accordingly, the obviousness-type double patenting rejection of record has been maintained.

#### **2. *Objection rejection***

The objection of claims 2, 4, and 15 because of proantocyanidine topographical error or misspelled proanthocyanidines is withdrawn in view of applicant's request and correction of the word.

#### **3. *Rejection under 112***

The rejection of claim 12 under 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention or because of insufficient antecedent basis for the limitation of the claim was remain rejected because of unpersuasive explanation.

#### **4. *Rejection under 35 U.S.C 103(a)***

Applicant argue there is no evidence in the cited references that the ascorbic acid is stable in the aqueous phase, the reference does not teach mixing a stable LAA with water, Furthermore, applicant argues that there is nothing in the teaching of Liu which suggest the use of a stable LAA in an aqueous medium.

Applicant's arguments filed 06/03/05 have been fully considered. However, applicants' arguments are not persuasive

Petrus discloses a composition comprising ascorbic acid, propylene glycol, EDTA, Glutathione and water, which read on the instant antioxidant, oxygen removing compound, metallic ion sequestering compound and oxidation reaction reverting compound respectively (column 14, lines 20-30 and illustrated examples 1 and 2 (column 115, lines 5-65). Petrus does not teach the claimed proanthocyanidines, however, teaches addition of other potent antioxidants such as glutathione, alpha-lipoic acid etc., to the composition (col. 10-11). Liu teaches stable antioxidant compositions comprising ascorbic acid, propylene glycol, disodium EDTA, and water, in addition to the antioxidants such as vitamin A. But fails to teach the claimed (OPC) proanthocyanidines. However, Liu Furthermore, teaches addition of chelating agents to each of the oil and water phases, addition of emulsifiers such as cetearyl alcohol and cetearyl glucoside, oil soluble antioxidants and water-soluble antioxidants such as sodium bisulfite, ascorbic acid, humectants including glycerol, propylene glycol (column 4, lines 5-65 and column 8, lines 5-65). Lerner teaches a skin care composition comprising ascorbic acid and proanthocyanidines, as the composition possesses a sunscreen and collagen repair properties. Lerner also teaches that both vitamin C and proanthocyanidines have superior free radical scavenging properties and are useful in collagen synthesis, optimum maintenance of immune system (abstract and column 2). Furthermore, Lerner teaches addition of propylene glycol, EDTA, xanthan gum etc., in the composition (column 3 and 4).

Applicant's arguments filed 06/03/05 have been fully considered. However, applicants' arguments are not persuasive because applicants did not argue the fact that the cited references disclose or suggest the components of the claimed composition. While the references teach composition comprising ascorbic acid, (OPC) proanthocyanidines, propylene glycol, EDTA, Glutathione and water, which read on the instant antioxidant compound, instant claims do not specifically distinguish the claimed composition from that of the prior art compositions so as render the compositions of prior art unsuitable for the claimed antioxidant compound. Absent any feature that limits the compositions specific to the claimed antioxidant compound, the invention has no patentable weight and the compositions of Lerner, Petrus, and Liu are suitable for antioxidant compound selected from the group consisting of levogyrous acid (LAA) and proanthocyanidines (OPC). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add proanthocyanidines of Lerner to the composition of Liu and Petrus comprising ascorbic acid because Lerner suggests that both the components have superior antioxidant activity and that a combination of vitamin C and proanthocyanidines result in an enhanced tissue healing response time, without any irritating side effects and yet long shelf life. Thus for the reasons stated above, applicant's argument are found unpersuasive and the prior art rejections are maintained.

*Suggestion*

An examiner suggested an applicants the limitation of claim 1 (to add claims 5, 7, and 8, to claim I), the limitation of claim 16 (to add claims 20, 22, and 23, to claim 16),

and the limitation of claim 28 (to add claims 31, 33, and 34 to claim 28). However, Applicants' response to the claims limitations is not persuasive.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### **Telephonic Inquiry**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Desta Yebassa whose telephone number is (571) 272-8511. The examiner can normally be reached Mon.-Friday 8:00 - 6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone Number for the organization where this application or proceeding is assigned is 703-

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872-9306.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for Published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should You have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, PhD  
Patent Examiner  
Art Unit 1615

  
THORMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
ARTER 1600